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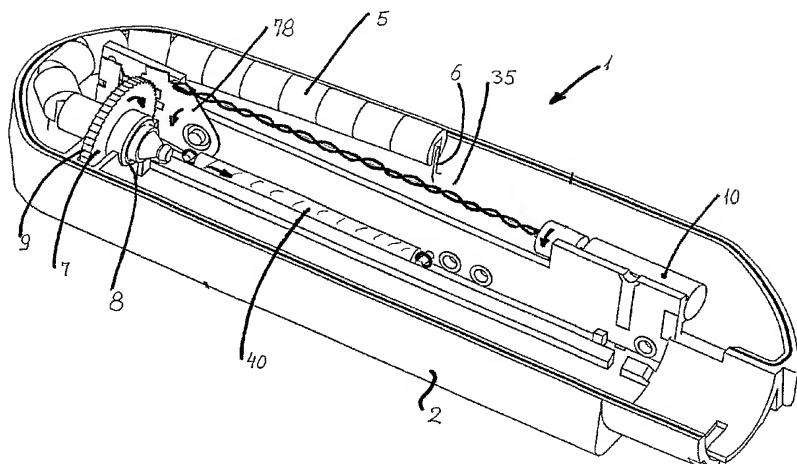
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- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND DEVICE FOR DISPENSING LIQUID MEDICINE BY MEANS OF A TWISTABLE ELEMENT



(57) **Abstract:** A method of dispensing liquid medicine comprising the steps of providing a wearable, disposable dispensing device comprising a syringe having a cylinder and a plunger displaceable in the syringe for pressing medicine out of the syringe cylinder and a drive mechanism connected to the plunger for displacing the plunger in the cylinder, and an electrical motor (10) connected to a battery and to the drive mechanism for providing a rotary force to the driving mechanism for displacing the plunger, the drive mechanism comprising one or more elongate twistable elements (35) such as a set of two or more strings, a flexible band and the like and having one end thereof connected to the electric motor for being twisted by the rotary force; displacing the plunger a certain distance in connection with a cycle of said driving mechanism comprising rotating the electrical motor in a first direction of rotation and subsequently rotating the electrical motor in the opposite direction of rotation.

WO 2006/105793 A1

METHOD AND DEVICE FOR DISPENSING LIQUID MEDICINE BY MEANS OF A TWISTABLE ELEMENT

The present invention relates to a method of dispensing liquid medicine
5 comprising the steps of providing a wearable, disposable dispensing device comprising a syringe having a cylinder and a plunger displaceable in said syringe cylinder for pressing medicine out of said syringe cylinder and a drive mechanism connected to said plunger for displacing said plunger in said cylinder, and an electrical motor connected to a battery and to said drive
10 mechanism for providing a rotary force to said driving mechanism for displacing said plunger, displacing said plunger a certain distance in connection with a cycle of said driving mechanism.

Methods of this type are known, wherein the electrical motor is controlled by a
15 control means so as to carry out a certain number of revolutions for each cycle corresponding to the desired distance of displacement of the plunger.

In connection with such methods it is important that no more than the predetermined amount of medicine be dispensed per cycle as otherwise life
20 threatening dosages may be dispensed.

When utilizing an electrical motor, a short circuit can entail that the motor does not stop after the predetermined number of revolutions or that the motor starts by itself.

25 Security means have been suggested to ensure that the predetermined dosage is not exceeded, for instance monitoring the amount of liquid dispensed per cycle or monitoring the displacement distance of the plunger or the amount of revolutions of the motor per cycle with interruption means being activated if the
30 monitored elements exceed a certain value.

There exists a need for a simple and fail-safe method to avoid over-dosage of medicine. One main object of the invention is to meet this need.

According to the invention this object is achieved by providing a drive mechanism comprising one or more elongate twistable elements having one end thereof connected to said electric motor for being twisted by said rotary force and by the cycle comprising rotating said electrical motor in a first 5 direction of rotation and subsequently rotating said electrical motor in the opposite direction of rotation.

Hereby, any short-circuit of the motor will not entail continued rotation of the motor in one direction with ensuing continued dispensing of medicine.

10

The invention further more relates to a wearable, disposable medicine dispensing device comprising:

- a syringe having cylinder and a plunger displaceable in the syringe cylinder for pressing medicine out of said syringe cylinder,
- 15 - a drive mechanism connected to said plunger for displacing said plunger in said cylinder, and
- an electrical motor connected to a battery and to said drive mechanism for providing a rotary force to said driving mechanism for displacing said plunger, and
- 20 - control means adapted for repeatedly reversing the direction of rotation of said electrical motor, said drive mechanism further comprising:
 - a set of twisted strings or a band connected at one end to rotation by said electrical motor and at the opposite end connected to a pivotable body, which is arranged for being pivoted between a first position and a second
 - 25 position by the reduction of the length of the twisted strings by the twisting thereof and by a spring in an opposite pivoting direction,
 - a ratchet wheel adapted for displacing a piston rod for displacing said plunger, and
 - a pawl on said pivotable body and arranged for engaging the teeth of said ratchet wheel, whereby the pivoting movement of said pivotable body rotates the ratchet wheel,
- 30 said control means comprising:

- at least one end stop electrical contact placed adjacent the position of the pivotable body when the twisted strings have a reduced length, and in the path of said body during the pivoting movement thereof, and
- electrical switch means for reversing the direction of rotation of said motor,

5 said switch means being electrically connected to said at least one end stop contact such that contact of said end contact means caused by the pivotable movement of the pivotable body reverses the direction of rotation of said motor.

10 In the following the invention will be described more in detail in connection with an embodiment shown, solely by way of example, in the accompanying drawings, where

15 Figs. 1-5 show a perspective view of an embodiment of the device according to the invention in different sequential states during a first half cycle during rotation of the electrical motor in a first direction of rotation,

20 Figs. 6a, b and c are views of some of the drive mechanism elements of the device in Figs. 1-5 in different states during the cycle.

Referring now to Figs. 1-5, a wearable disposable dispensing device for medicine referred to generally by the numeral 1 and of the type described in WO 2004/041330 and WO 2004/065412, the disclosure of which is hereby incorporated herein by reference, comprises a housing 2, where only the 25 bottom half is shown for the sake of clarity. A cylindrical medicine container or carpule having at one end a silicone body for receiving a catheter for dispensing medicine from the interior of the carpule to a human body and being open at the opposite end to receive a flexible piston rod 5 for displacing an internal not shown plunger or piston in the carpule for forcing medicine out 30 through a catheter needle assembly connected to the silicone body can be placed in the housing 2.

The flexible piston 5 is composed of segments hinged together and outwardly threaded guided by a rail 6 received in recesses in each of the segments of the rod 5. The not shown outward threads of the segments of the flexible piston rod 5 engage in a thread 8 of ratchet wheel 7 having teeth 9 along the periphery 5 thereof.

Referring to Figs. 1-6, the electrical motor 10 is electrically connected to a battery and control means and the axle of the motor is connected to a pair of twisted strings 35 or a band or similar device, which reduces its length when 10 twisted and increases its length when untwisted, said length variation being provided by the rotation of the motor, i.e. the device is connected to the rotating axle of the motor at one end and connected to a pivotable body 78 at the opposite end. The pivotable body is provided with an extension 78a comprising a pawl 74 arranged to engage the teeth 9 on the ratchet wheel 7, as indicated 15 in Figs. 6a, 6b, 6c, whereby the pivoting of the pivotable body 78 provides a rotation of the ratchet wheel 7. A second pawl mechanism 72, 84 is provided to prevent rotation of the ratchet wheel 7 in the opposite direction, again as shown in Figs. 6a-6c.

20 The displacement of the pawl 74 between the two positions indicated in Figs. 6a and 6b is provided by the reduction of the length of the twisted strings 35 by rotation of the motor and the displacement in the opposite direction is provided by the spring 40 during extension of the twisted strings 35 provided by rotation of the motor in the opposite direction, whereafter further rotation in this direction 25 again reduces the length of the twisted strings 35, whereby a complete cycle of rotation in one direction of the motor provides a movement of the pivotable body from the position shown in Fig. 6a to the position shown in Fig. 6b and back to the position shown in Fig. 6a, this movement being provided by the twisted strings 35 being untwisted and twisted in the opposite direction during 30 rotation of the motor in one direction. Thus, the rotation of the motor in one direction of rotation provides a full stroke for the pivotable body and thus the pawl mechanism moving the ratchet wheel one step forward and the following

rotation of the motor in an opposite direction of rotation provides a further full stroke of the pivotable body and the pawl mechanism.

Thus, during one cycle of rotation in one direction and the opposite direction of

5 the electrical motor 10, the ratchet wheel 7 will be advanced by two teeth corresponding to two displacements of the pawl 74. The pivotable body 78 comprises a protuberance 78a which co-operates with two end stop contacts 85a and 85b electrically connected to the control means for controlling the reversal of the direction of rotation of the electrical motor when the

10 protuberance 78a contacts the end stop contact 85a. Due to the fact that the twisted strings 35 can only provide a pulling force on the pivotable body 78, a spring 40 is connected to the pivotable body to provide the movement in the direction shown by the arrow in Fig. 1.

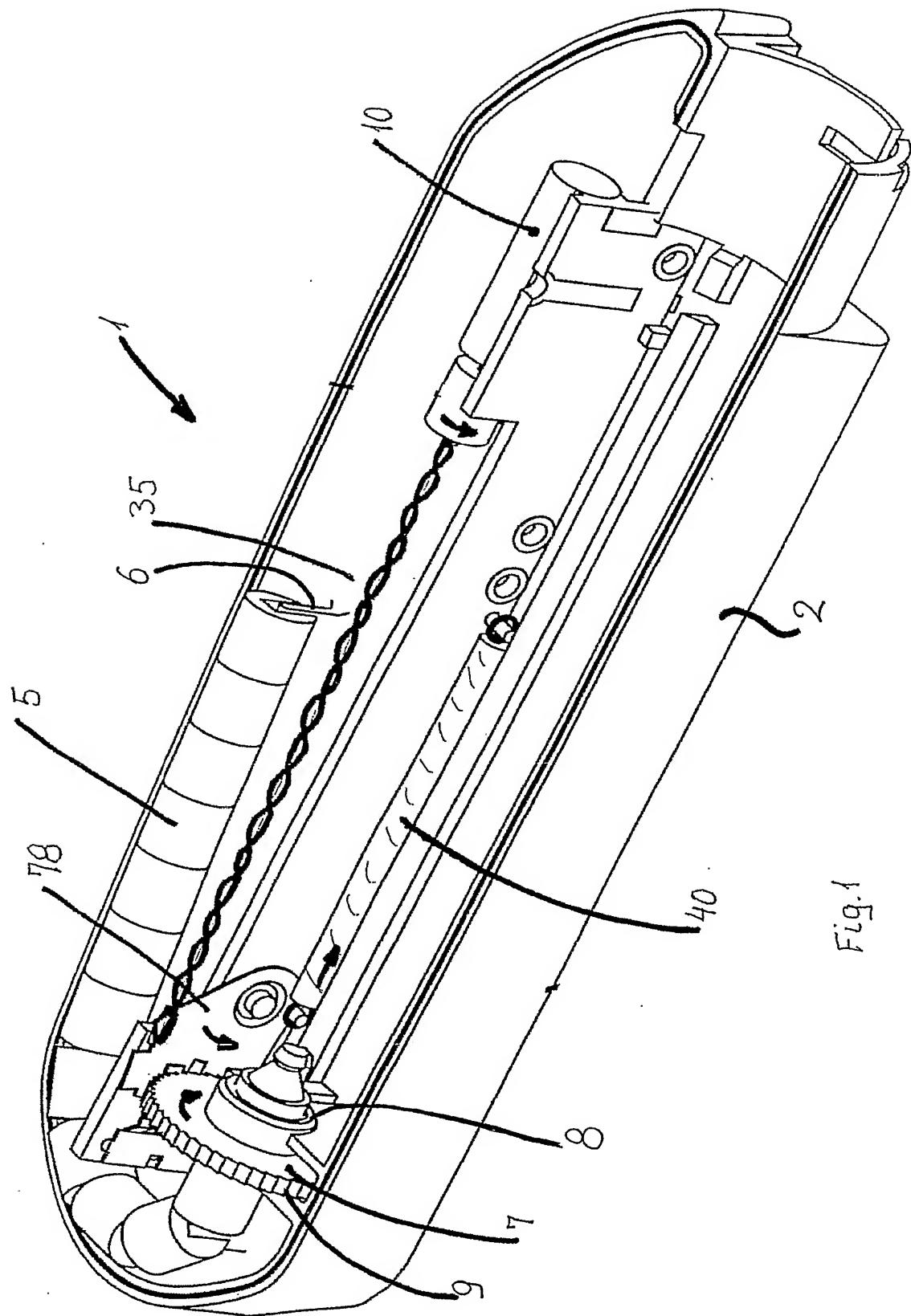
15 In the embodiment shown in the figures spring 40 is a coil spring, however, other types of springs, such as a rod spring could be provided for this purpose.

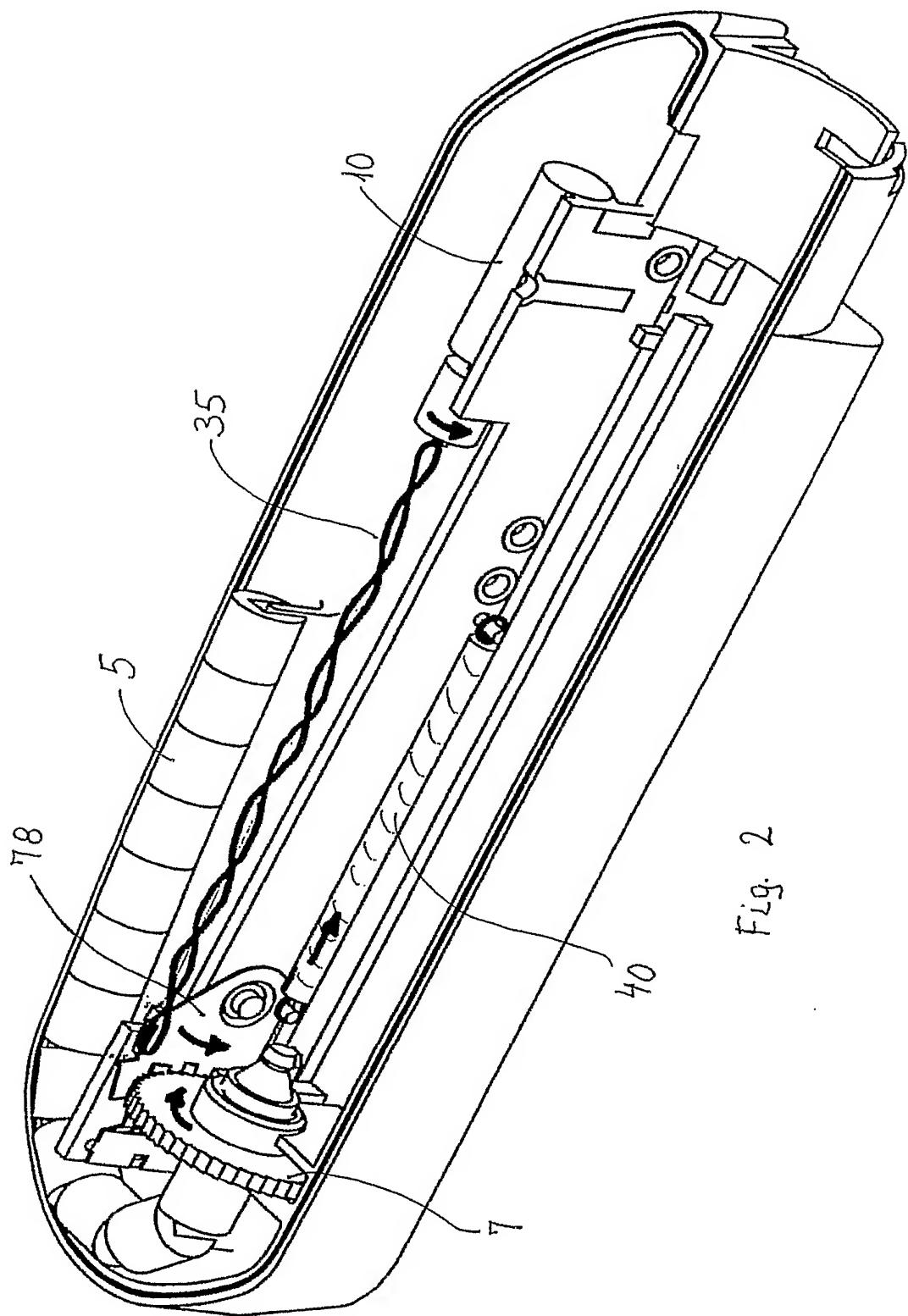
CLAIMS

1. A method of dispensing liquid medicine comprising the steps of:
 - 5 - providing a wearable, disposable dispensing device comprising a syringe having a cylinder and a plunger displaceable in said syringe cylinder for pressing medicine out of said syringe cylinder and a drive mechanism connected to said plunger for displacing said plunger in said cylinder, and an electrical motor connected to a battery and to said drive mechanism for providing a rotary force to said driving mechanism for displacing said plunger, said drive mechanism comprising one or more elongate twistable elements having one end thereof connected to said electric motor for being twisted by said rotary force,
 - 10 - displacing said plunger a certain distance in connection with a cycle of said driving mechanism comprising rotating said electrical motor in a first direction of rotation and subsequently rotating said electrical motor in the opposite direction of rotation.
2. A method according to claim 1 comprising the additional step of
 - 20 - repeating said cycle the number of times necessary to displace said plunger the distance corresponding to a required volume of medicine to be dispensed.
- 25 3. A wearable, disposable medicine dispensing device comprising:
 - a syringe having cylinder and a plunger displaceable in the syringe cylinder for pressing medicine out of said syringe cylinder,
 - a drive mechanism connected to said plunger for displacing said plunger in said cylinder, and
- 30 - an electrical motor connected to a battery and to said drive mechanism for providing a rotary force to said driving mechanism for displacing said plunger, and

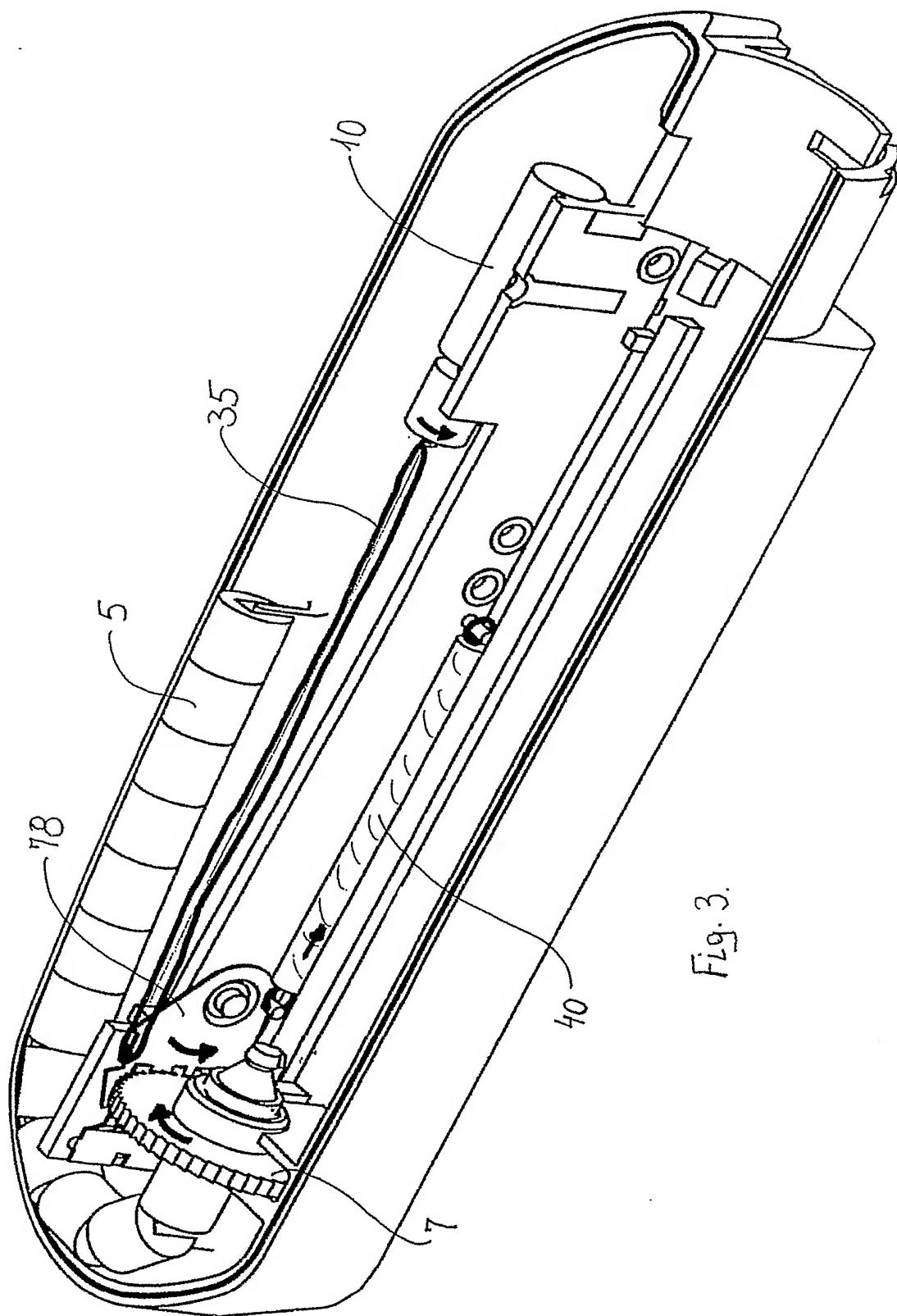
- control means adapted for repeatedly reversing the direction of rotation of said electrical motor, said drive mechanism further comprising:
- a set of twisted strings or a band connected at one end to rotation by said electrical motor and at the opposite end connected to a pivotable body, 5 which is arranged for being pivoted between a first position and a second position by the reduction of the length of the twisted strings by the twisting thereof and by a spring in an opposite pivoting direction,
- a ratchet wheel adapted for displacing a piston rod for displacing said plunger, and
- 10 - a pawl on said pivotable body and arranged for engaging the teeth of said ratchet wheel, whereby the pivoting movement of said pivotable body rotates the ratchet wheel,
said control means comprising:
- at least one end stop electrical contact placed adjacent the position of the 15 pivotable body when the twisted strings have a reduced length, and in the path of said body during the pivoting movement thereof, and
- electrical switch means for reversing the direction of rotation of said motor, said switch means being electrically connected to said at least one end stop contact such that contact of said end contact means caused by the 20 pivotable movement of the pivotable body reverses the direction of rotation of said motor.

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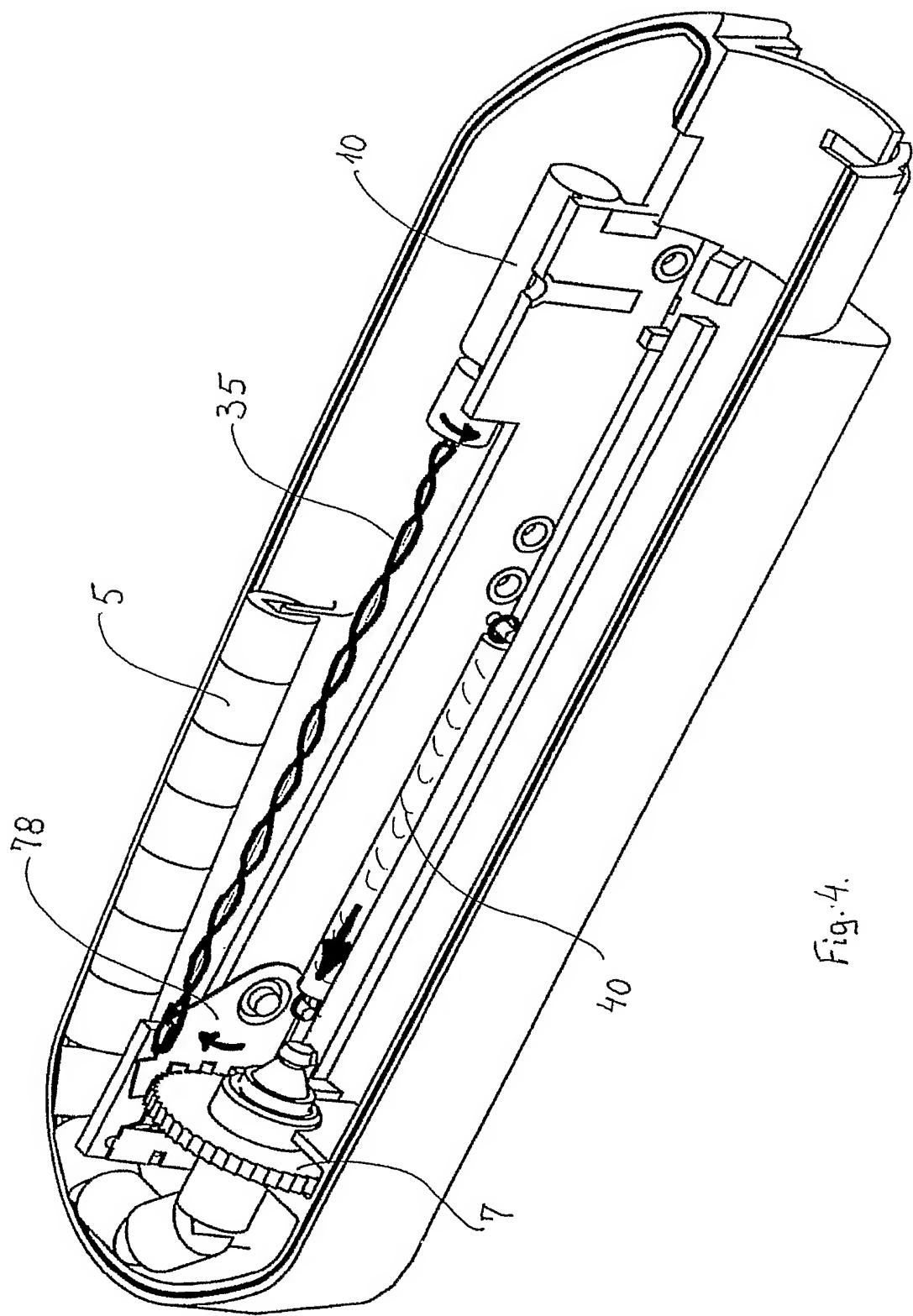


Fig. 4.

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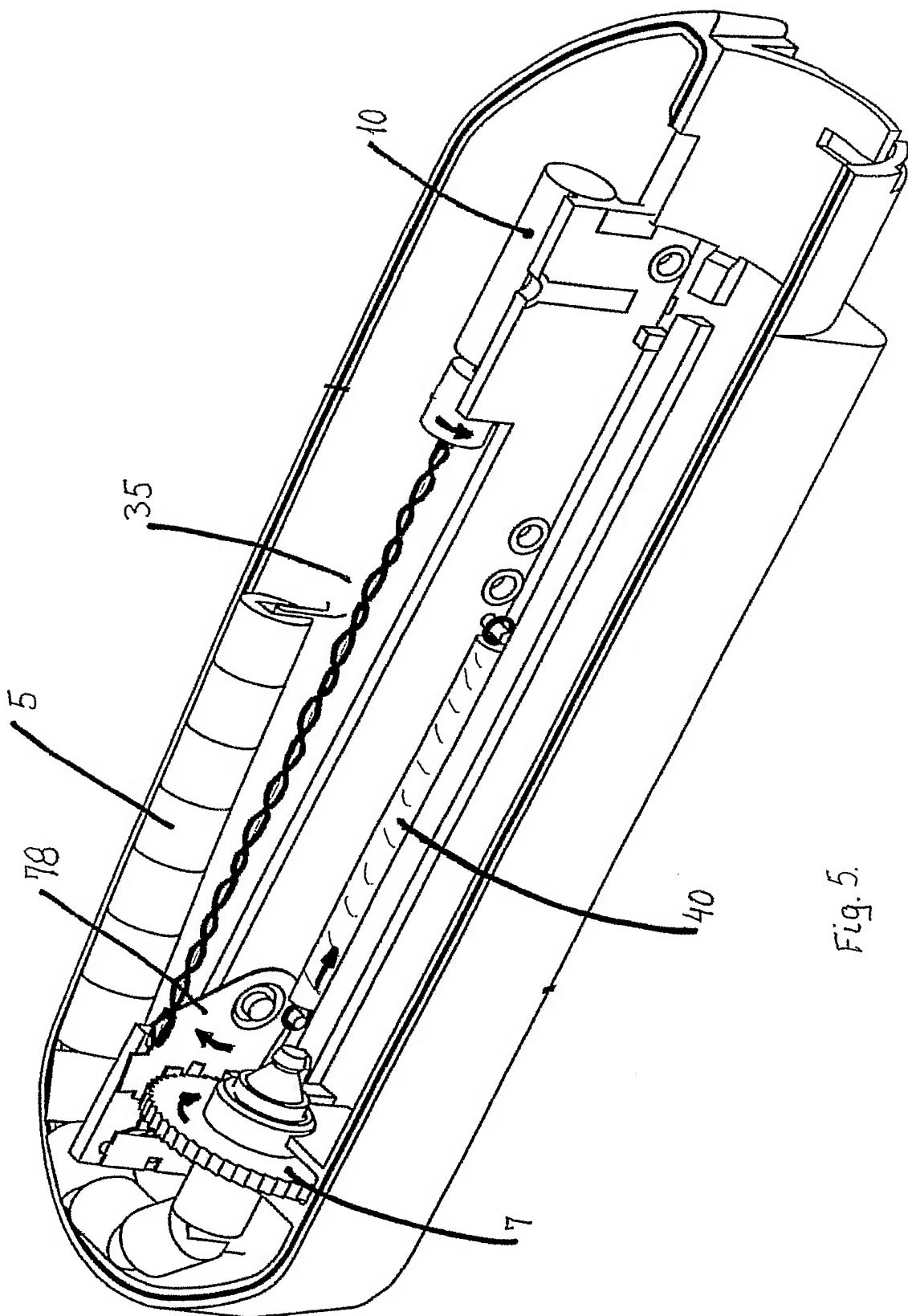
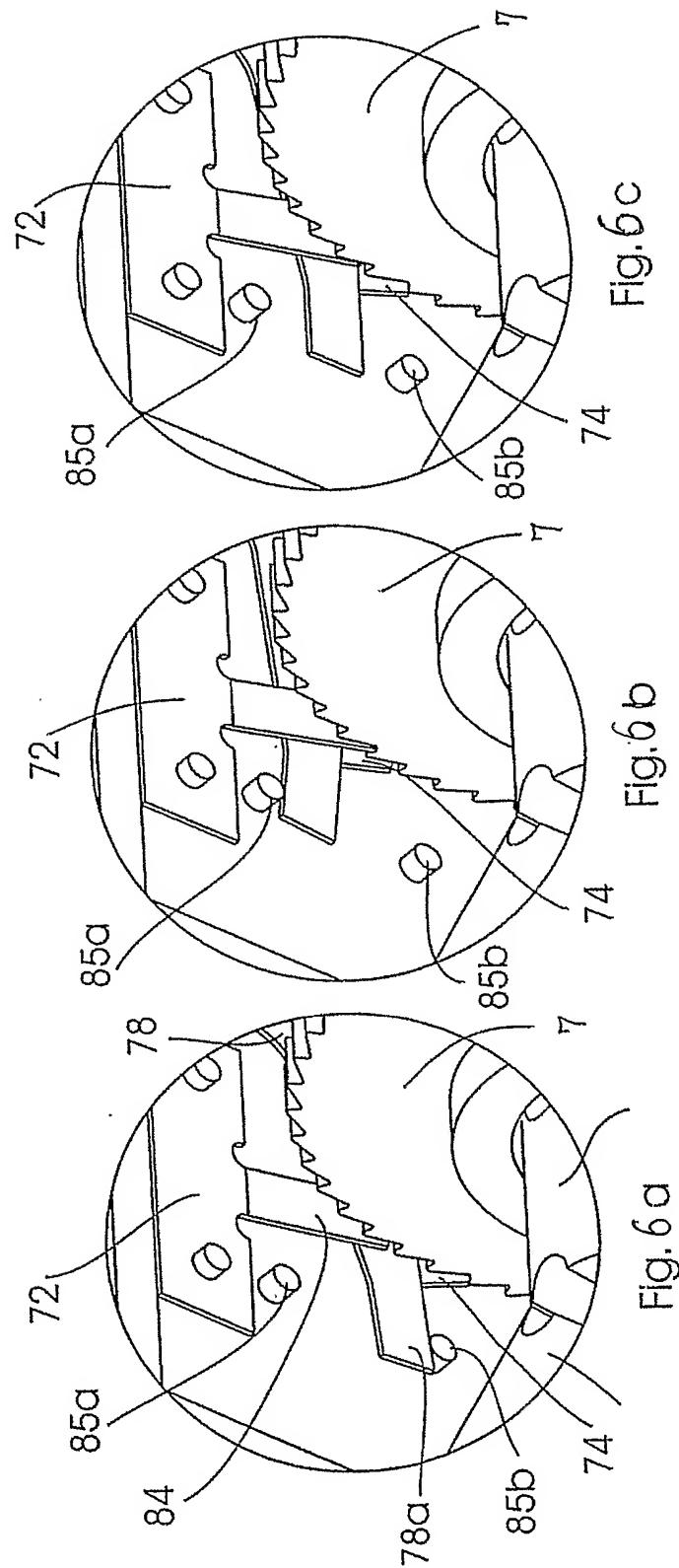


Fig. 5.

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INTERNATIONAL SEARCH REPORT

International application No
PCT/DK2006/000194

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/142

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 313 439 A (BABB ET AL) 2 February 1982 (1982-02-02) abstract; figure -----	3
Y	GB 747 701 A (LINES BROS. LIMITED) 11 April 1956 (1956-04-11) page 1, line 60 – line 75; figure 1 -----	3
Y	US 5 261 882 A (SEALFON ET AL) 16 November 1993 (1993-11-16) abstract; figures -----	3
Y	WO 2004/056412 A (M2 MEDICAL A/S; MERNOEE, MORTEN; LYNGSIE, MICHAEL, GORM) 8 July 2004 (2004-07-08) cited in the application abstract; figures ----- -/-	3

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

20 July 2006

Date of mailing of the international search report

01/08/2006

Name and mailing address of the ISA/

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INTERNATIONAL SEARCH REPORT

International application No
PCT/DK2006/000194

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	WO 2005/072795 A (M 2 MEDICAL A/S; MERNOEE, MORTEN) 11 August 2005 (2005-08-11) the whole document -----	3

INTERNATIONAL SEARCH REPORT

International application No.
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Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 1, 2
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/DK2006/000194

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
US 4313439	A 02-02-1982	NONE			
GB 747701	A 11-04-1956	NONE			
US 5261882	A 16-11-1993	NONE			
WO 2004056412	A 08-07-2004	AU 2003287926 A1 CN 1738656 A EP 1583571 A2 JP 2006511263 T US 2005273059 A1			14-07-2004 22-02-2006 12-10-2005 06-04-2006 08-12-2005
WO 2005072795	A 11-08-2005	NONE			